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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
09/381,794	12/27/99	HUNTER	454313-2540

EXAMINER

020999
FROMMER LAWRENCE & HAUG
745 FIFTH AVENUE
NEW YORK NY 10151

HM12/0606

ART UNIT	PAPER NUMBER
1615	12

DATE MAILED: 06/06/01

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 4/24/01

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire _____ month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 22-49 is/are pending in the application.
Of the above, claim(s) 24-27,29,30&37 is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 22,23,28,31-36,38-49 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

Receipt is acknowledged of Change of Address, Request for Time and Amendment, and Power of Attorney (4/24/01).

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119 E or 120 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78).

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's election with traverse of methods and fipronil species in Paper No. 10 is acknowledged. The traversal is on the ground(s) that inefficiency and unnecessary expenditures to applicant and PTO wold result, as well as extreme prejudice in view of GATT. This is not found persuasive because extensive time and effort are required to search each of the independent and patentably distinct species and inventions, in different classes ad subclasses no matter the expenditures.

The requirement is still deemed proper and is therefore made FINAL.

Claims 24-27, 29, 30, 37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 10.

Claims 32, 45-47 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 32 refers to claim 1 canceled. There is no "2nd" active in claim 45-47. There is no longer antecedent basis for "compound of formula II" , at claim 32.

Claims 22, 23, 28, 31-36, 48-49 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are beyond the scope of the specification; dosages and treatment protocols, the mix and ratio's of added compound, are not sufficiently presented to permit expectation of the claimed premise eradication, by application only to the animal of topical spot on preparation. Only fipronil alone has been shown effective only for eradication on the dog and cat; these determinations are granted as within the scope of the skilled artisans to perform, but no indication is shown, for cats or dogs, of ratios and dosages o f fipronil to the various claimed added insecticides, and certainly not for other domestic and lab animals goat, horse, guinea pigs, rabbit--without this information, one could readily see either ineffective premise control or dead animals.

Claim 45 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 49-68 of U.S. Patent No. 6096329. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent encompasses the instant claims.

Claims 22, 23, 28, 31-36, 38-39, 42, 43 and 49 are rejected under 35 U.S.C. 102(b) as being anticipated by Frontline.

Frontline is a spot-on, applied monthly to control flea infestation of dogs, remaining or animal even after bathing, as it collects and remains in follicles.

Claims 22, 23, 28, 31-36, 38-43, 48 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frontline (TOP-SPOT) in view of Meo `96 and Postal et al `95.

Frontline, shown for dogs, obviously was also available in smaller dosages , as also for smaller dogs, and is the instant active, applied by the same method, as a spot-on formulation.

Meo shows the fipronil provides for dogs and cats, significant premise flea control--there is no difference between the applicants methods, claiming premise eradication, and that of Meo, as supported in the specification; but Meo has less than 100% (98%) eradication while specification has no report of premise flea presence or absence--determination was dog flea count. Postal further shows cat and dog affectively treated.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made desiring to utilize flea protection of premises to use fipronil (Frontline), Postal showing

as well known by the prior art. Meo teaches one having ordinary skill in the art would be motivated to perform this modification in order to increase efficacy over other products.

All the critical elements of the instant are disclosed. The amounts and proportions of active ingredients are result effective parameter chosen to obtain the desired effects. It would be obvious to vary the dosage to optimize the effect desired, depending upon the particular pest of interest, concern for toxicity, cost minimization, enhances, and prolonged efficacy.

Claims 22, 23, 43-47 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sirlinyan et al DE 44443888.

One of the instant compound III, imidacloprid, with either avermectins, juvenile hormones, or chitin synthesis inhibitors (p. 7, line 37-50, p. 8, top). The compositions can treat fleas (line 38), and constitute the instant solvent and adjuvant ingredients (p. 3, 4). Thus applicable as is known in he art, to the animal of concern.

Claims 22, 23, 43-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirinyan et al DE 4443888 in view of Mencke et al 5912295.

Sirinyan, above, provides the instant compositions effective against fleas, but does not explicitly use the instant claim language. However, Mencke also show imidacloprid (col. 4, line 19-24) applied to domestic and laboratory animals (col. 6, line 20-26) administered by pour on or spot on formulation (col. 7, line 52-54), with ethanol, glycerol, benzyl alcohol mixtures. The instant crystallization inhibitors solvents and co-solvents (col. 8, line 12-16); and antioxidants (col. 8, line 54-59).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made desiring to maintain healthy pets, to use Sirinyan's flea control compositions with the endoparasiticide of Mencke, in topical, spot-on formulation, in order to protect in one application, ecto and endo parasites of pets.

The particular % mix of active, is a function of the compatibility of these ingredients with the adjuvants and solvents suitable for veterinary spot-on use.

Claims 22, 23, 28, 31-36, 43-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Senbo 5567429 in view of Mencke et al 5712295.

Senbo provide formulation mixes of fipronil and derivatives, and juvenile hormones and chitin synthesis inhibitors (col. 1, A, B, C and line 57-line 30, col. 2), effective at low doses (line 7-9) against fleas of cat and rat and dog (line 59-62). Senbo didn't treat the animal. Mencke (above) does, and shows also advantageous use of endoparasiticides of the instant application, in spot on formulation.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made desiring to control fleas of pets at low doses, to utilize Senbo's combination, with added advantages of Menckes spot on formulation to also control endoparasites. Motivation to combine is suggested by Senbo--reduce the dose of the active ingredient in order to provide pest efficacy but reduced pet toxicity.

Claims 22, 23, 28-36, 38-49 are rejected under 35 U.S.C. 102(e) as being anticipated by Steller et al 5939441 in view of Mizutan-WO 96/16544 and Hatton et al EP 0295117.

Steller shows the instant compounds of formula I (col. 1, 2) with juvenile hormone mimies, chitin synthesis inhibitors and avermectins (col. 11) at the instant concentration, are effective against fleas (col. 6, line 16-18) of pets (col. 7, line 42-45). Formulations include spot-on (line 60, col. 71 with the instant solvents/adjuvants (col. 8) applied in known fashion (col. 11, bottom). The residual action is better than that of (Example A) fipronic, thus application at less than daily intervals, yet often enough to control fleas, would be within the skill of one in the art to practice.

Mizutain teaches fipronic effective to control fleas on dogs/cats by application of 0.1-100 mg/kg (p. 5, line 25-30). The instant crystallization inhibitors and solvents are used (p. 3, 4). Hatton also (cpd 52) uses fipronic with avermectins (top, page 8) at the instant dosage, daily (line 27-33). See Example 9 and compositions (p. 9) (p. 7) to control fleas.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made desiring to utilize insecticidal protection of pets, to use Steller or Hatton, modified with the adjuvants shown by Mizutani useful for compositions able to be applied to pets to control fleas.

Applicant's arguments filed 4/16/01 have been fully considered but they are not persuasive. Applicants arguments have been carefully considered, with rejection reformulated in view of amendments. Although he compounds are seen as patentably distinct, where others are seen with the claimed secondary actives or fipronic, they have been cited, since the claims are not limited to fipronil. Applicant's argument (p. 10) to R3 as ethyl, is not relevant to the fipronil structure, but

rather to formula II (see p. 4 of specification . Limitation to the desulfinyl fipronil will be considered, as equivalent to fipronil. The amendments necessitated new art, and modification, but the claims to premise eradication are seen as no better, as they are supported, than the cited prior art--only animals are treated, and no premise examination for ova or fleas is evident in either case.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Neil Levy whose telephone number is (703) 308-2412. The examiner can normally be reached on Tuesday to Friday from 7 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees, can be reached on (703) 308-4628. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Levy:mv

June 1, 2001

NEIL S. LEVY
PRIMARY EXAMINER